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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/675,705 | 09/30/2003 | Mark S. Ortiz | END5102.0515147 | 6304 |

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| EXAMINER |
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POUS, NATALIE R

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| ART UNIT | PAPER NUMBER |
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3731

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/675,705 | Applicant(s) ORTIZ, MARK S. | |
| | Examiner Natalie Pous | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>10/18/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group 1, apparatus in the reply filed on January 26, 2006 is acknowledged. Applicant's submission of amendments to the claims is also acknowledged. A first action on the merits of elected claims 1-20 follows.

Specification

2. The attempt to incorporate subject matter into this application by reference to co-pending and commonly owned applications is ineffective because the serial numbers are not presented in the specification.

Drawings

3. The drawings are objected to because several characters are crossed out or scribbled through, making some of the characters difficult to read. For example, fig. 1, the distal hinge is inferred to be referenced by character 44, but that number is not clear in the drawings. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the

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renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 7, 9-11 and 20 rejected under 35 U.S.C. 102(b) as being anticipated by Huebsch.

5. Regarding Claim 1, Huebsch teaches an anastomosis device comprising: a proximal ring (16); a distal ring (14); a plurality of proximal arms (22) each attached to the proximal ring at one end and having a distally directed other end; a plurality of distal arms (22) attached to the distal ring at one end and having a proximally directed other end; a center portion (18) coupling the proximal end of each distal arm to the distal end of each proximal arm; and a latching mechanism (128) operably configured to lock at a reduced longitudinal spacing two selected from a group consisting of the proximal ring, the distal ring, and the center portion; wherein the anastomosis device forms a

cylindrical shape when unactuated (fig. 2) and wherein the proximal and distal arms each outwardly extend when actuated to form a rivet shape (fig. 4).

Regarding Claim 2, Huebsch teaches the anastomosis device of claim 1, wherein the center portion comprises a center ring (18) aligned and interposed between the proximal (16) and distal (14) rings.

Regarding Claim 3, Huebsch teaches the anastomosis device of claim 2, wherein the proximal arms are radially aligned with the distal arms (fig. 3)

Regarding Claim 6, Huebsch teaches the anastomosis device of claim 1, wherein the device is formed from polymer material (Column 2, proximate lines 23-28).

Regarding Claim 7, Huebsch teaches the anastomosis device of claim 6, wherein the device is formed from biofragmentable material (Column 7, proximate lines 44-50).

Regarding Claim 9, Huebsch teaches the anastomosis device of claim 1, wherein the latching mechanism comprises at least one interiorly disposed hook (128).

Regarding Claim 10, Huebsch teaches the anastomosis device of claim 1, wherein the latching mechanism comprises an interference fit (122, 124) formed between rings.

Regarding Claim 11, Huebsch teaches the anastomosis device of claim 1, wherein the proximal and distal arms (22) each include a hinge (24).

Regarding Claim 20, Huebsch teaches an anastomosis ring device, comprising; a proximal arm (16, 22) means for engaging a first lumen; a distal arm means (14, 22) for engaging a second lumen; and a latching means (128) maintaining the proximal and distal arm means in an actuated condition to cause anastomosis.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 8, 13 and 16-19 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Huebsch et al (US 5853422). Claims 8, 13, 14 and 16-19 are being treated as a product by process limitation, in that the "sheet material, cylindrically formed onto a mandrel, and opposing longitudinal edges attaches one to another," or the "generally rectangular substrate of material," wherein "connecting opposite lateral edges comprises fusing," and "forming laterally aligned hinge portions," and "forming separations in the center portion that communicate with the separations in both the proximal and distal arms portions to allow the center portion to dilate when actuated" refer to the process of making the device and not to the final product created. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of

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patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (See MPEP §2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

Thus, in this case, a device made from a rectangular sheet of material with fused edges is directed to the method of making the device and not the final product made. It appears the product disclosed by Huebsch would be the same and would perform equally well as that *claimed*; especially since both applicant's product and the prior art have the same final shape and structure of a device having proximal, distal and central rings, with longitudinally extending arms connecting the rings.

8. Claims 4, 5, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch in view of Berg (US 6712836).

Regarding the limitation wherein the proximal arms are radially staggered with the distal arms, Huebsch teaches all limitations of preceding dependent claim 1, as previously described, but fails to disclose wherein the proximal arms are radially staggered with the distal arms. Berg teaches a device wherein the proximal extending tissue contacting portions (108) are staggered with respect to the distal extending tissue contacting portions (110) as seen in fig. 6 in order to limit tissue damage on both sides of the tissue. It would have been obvious to one of ordinary skill in the art at the time

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the invention was made to modify the device of Huebsch with staggered tissue connecting portions on the proximal and distal sides in order to limit tissue damage on both sides of the tissue.

Regarding the limitations wherein device comprises a radiopaque material, Huebsch teaches all limitations of preceding dependent claims 1 and 13 as previously described, but fails to disclose wherein the device comprises a radiopaque target material. Berg teaches a device comprising a radiopaque material in order to view the device during deployment using imaging techniques to determine the device is deployed at the proper location. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Huebsch with a radiopaque material as taught by Berg in order to view the device during deployment using imaging techniques to determine the device is deployed at the proper location

9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch in view of Barra et al. (US 5843088). Huebsch teaches all limitations of preceding dependent claims 1 and 11 as previously described, but fails to disclose wherein a pad is outwardly disposed on each inner arm segment. Barra teaches a device wherein pads (6) are disposed on the portion touching tissue in order to gently rest the device on the tissue. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Huebsch with pads on the portion of the device touching tissue in order to allow the device to gently rest on the tissue.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRP
2/13/06



(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER